IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE EGALET CORPORATION SECURITIES LITIGATION	**CIVIL ACTION** **NO. 17-390**

MEMORANDUM RE: DEFENDANTS' MOTION TO DISMISS AND PLAINTIFFS' MOTION TO STRIKE

Baylson, J. **August 2, 2018**

I. Introduction

In this securities case, brought pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, a putative class of shareholders possessing shares of Egalet Corporation ("Egalet") alleges that three of Egalet's executives defrauded the class by failing to disclose that the FDA was likely to grant intranasal labeling exclusivity to a competitor's abuse-deterrent morphine drug. As a result, upon FDA approval of Egalet's own pain management drug, Egalet was not permitted to market its drug as effective at reducing intranasal opioid abuse, and when this news was announced, shares of the stock dropped significantly within a matter of days.

Presently before the Court are Defendants' Motion to Dismiss, and Plaintiffs' Motion to Strike one of the exhibits that Defendants attached to their Motion to Dismiss.

For reasons discussed below, Plaintiffs' Motion to Strike is DENIED and Defendants' Motion to Dismiss the Amended Complaint is GRANTED WITH PREJUDICE.

II. Procedural History

This case began on January 27, 2017, with the filing of a Class Action Complaint (ECF 1) by Plaintiff George Mineff against Robert S. Radie ("Radie"), Stanley J. Musial ("Musial"),

Jeffrey M. Dayno ("Dayno," and together with the aforementioned individuals, "Individual Defendants"), and Egalet (together with Individual Defendants, "Defendants"). On February 10, 2017, Plaintiff Steve Klein filed a Class Action Complaint against Defendants in a separately captioned case (17-cv-617, ECF 1), which was designated as related and assigned to the undersigned. On March 28, 2017, two sets of movants filed motions for consolidation of the related cases, appointment of lead plaintiffs, and approval of their respective selections of legal counsel. (ECF 10-11) However, the first of the two motions was withdrawn on April 11, 2017. (ECF 15) Also on April 11, 2017, Defendants filed a response to the remaining motion, expressing their agreement that the related actions should be consolidated. (ECF 16)

On May 1, 2017, this Court granted the motion of Johseph Spizzirri, Abdul Rahiman, and Kyle Kobold (collectively, "Egalet Investor Group"), thereby consolidating the two related cases under the above caption, appointing Egalet Investor Group as Lead Plaintiff, and approving their selection of counsel. (ECF 17) On May 15, 2017, pursuant to a joint stipulation of the parties, this Court granted leave to Lead Plaintiff to file an amended complaint. (ECF 18) Lead Plaintiff filed its Consolidated Amended Class Action Complaint on July 3, 2017. (ECF 19, "CAC") The Amended Complaint contains two counts: (1) "Violations of Section 10(b) [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5] Promulgated Thereunder Against All Defendants," and (2) "Violations of Section 20(a) [15 U.S.C. § 78t(a)] Against the Individual Defendants." (Id.)

Presently before the Court are three motions. The first two motions are (1) Defendants' Motion to Dismiss the Amended Complaint, which was filed on September 1, 2017; and (2) Plaintiffs' Motion to Strike Exhibit 1 to Defendants' Motion to Dismiss, or in the Alternative, to Treat Defendants' Motion to Dismiss as a Motion for Summary Judgment, which was filed on October 31, 2017. (ECF 24, "MTD"; ECF 26, "MTS") The parties submitted Responses and

Replies to each motion. (ECF 25, "MTD Response"; ECF 28, "MTS Response"; ECF 29, "MTD Reply"; ECF 31, "MTS Reply")

On February 20, 2018, the Court held oral argument on both motions. (ECF 39) During oral argument, Plaintiffs represented to the Court that they would like to avail themselves of the opportunity to file a second amended complaint. Thereafter, on March 6, 2018, Plaintiffs filed the third motion now before the Court, a Motion for Leave to File a Second Amended Complaint (ECF 43), to which they attached a proposed third complaint. Defendants filed a Response (ECF 44) on March 20, 2018, and Plaintiffs filed a Reply on March 27, 2018. (ECF 45) Plaintiff also filed a Motion for Leave to File a Surreply (47), which this Court granted on April 4, 2018. (ECF 48).

On July 12, 2018, this Court held oral argument on all open motions, specifically addressing with the parties those portions of the proposed Second Amended Complaint which do not appear in the First Amended Complaint. Because Defendants' Motion to Dismiss is addressed to the First Amended Complaint, it is the principal subject of this opinion. The proposed Second Amended Complaint, which almost entirely mirrors the First Amended Complaint, is discussed *infra* in the context of whether amendment would be futile.

III. Factual History[1]

A. The Parties

Plaintiffs are a class of persons who purchased or otherwise acquired shares of Egalet common stock between November 4, 2015, and January 9, 2017, inclusive (the "Class Period"). (CAC ¶ 1)

Defendant Radie has served as Egalet's CEO, President, and a member of its Board of Directors since March 2012. (Id. ¶ 24)

Defendant Musial has served as Egalet's Executive Vice President since December 2015, CFO since April 2013, and Principal Financial Officer and Secretary since September 2013. (Id. ¶ 25)

Defendant Dayno has served as Egalet's Chief Medical Officer since July 2014. (Id. ¶ 26)

Defendant Egalet is a specialty pharmaceutical company that focuses on developing and commercializing abuse-resistant formulations of opioids and other pain care drugs. (CAC ¶ 33) Egalet's proprietary Guardian Technology employs a novel application of "injection molding" to manufacture "tablets that are hard and difficult to manipulate for misuse and abuse." (Id. ¶ 34)

"At the beginning of the Class Period," Egalet was developing two late-stage lead product candidates: ARYMO ER™ and Egalet-002. (Id. ¶ 35) Both use Guardian Technology to impede abuse. (Id.) Egalet also acquired two FDA-approved pain care products. (Id. ¶ 36)

[1] All facts are drawn from the Consolidated Amended Complaint (ECF 19, "CAC"), and, for purposes of this motion, the Court accepts as true the facts contained therein. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

Plaintiffs' Amended Complaint centers on ARYMO ER™ ("ARYMO"). Egalet developed ARYMO as an extended release morphine tablet intended to utilize Guardian Technology to deter abuse of the product by increasing resistance to physical methods of manipulation (e.g., cutting, crushing, grinding), chemical manipulation, and extraction. (Id. ¶ 34)

B. The 505(b)(2) Pathway to Drug Approval

In 1984, Congress passed the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984). (See id. ¶ 47) The Hatch-Waxman Amendments require that a drug manufacturer seeking to market a new drug must first obtain approval from the Food and Drug Administration ("FDA"). (Id. ¶ 48) A manufacturer can obtain FDA approval via any of three different application pathways, one of which is known as a Section 505(b)(2) New Drug Application ("NDA"). (Id.)

An applicant for a 505(b)(2) NDA can receive approval for marketing a new drug even where one or more investigations relied upon for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." (Id. ¶ 51) Thus, a 505(b)(2) NDA applicant can rely on previously published reports of studies and the FDA's own findings with respect to drugs that the FDA has previously approved. (Id.) When an applicant relies on clinical studies that were previously submitted to the FDA in support of a different drug, the drug for which the borrowed studies were conducted is referred to as the "Reference Listed Drug" ("RLD"). (Id. ¶ 52) A 505(b)(2) NDA applicant may proffer studies conducted on the RLD to satisfy the applicant's burden of proving a new drug's safety and effectiveness. This generally occurs when

the new drug differs only slightly from the RLD, such as a drug product innovation or change in drug strength. (Id. ¶ 54)

C. Marketing Exclusivity

The Hatch-Waxman Amendments create certain incentives to encourage innovation of new drug products. (See id. ¶ 55) One of those incentives is "marketing exclusivity," which the FDA can grant to new drugs that it approves. (Id. ¶ 54-55) Marketing exclusivity, as its name suggests, provides exclusive marketing rights over a drug. (Id. ¶ 55) It can prevent the issuance of requested labeling language sought by another applicant or prevent the submission or effective approval of other NDAs (such as 505(b)(2) NDAs). (Id.) In other words, when the FDA grants marketing exclusivity to a drug, it confers substantial benefits on the drug. (Id.)

For a drug to receive exclusivity, it must meet all statutory requirements and receive approval by the FDA. (Id. ¶ 57) There are four categories of exclusivity, one of which is referred to as "Other Exclusivity." (Id.) One type of "Other Exclusivity" is "new drug product exclusivity." See 21 C.F.R. § 314.108(b)(4). (Id. ¶ 58) New drug product exclusivity is granted when a 505(b)(2) NDA: (1) contains an active moiety (a sub-division of a molecule) that has previously received FDA approval; (2) includes new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant that were "essential to the approval of the application"; and (3) is approved by the FDA. (Id. ¶ 58) If these three conditions are met, the FDA will not approve another 505(b)(2) NDA with the same "conditions of approval" for a period of three years from the date of the application's approval. (Id. ¶ 58)

21 C.F.R. § 314 further defines several of the constituent terms in the second condition above—i.e., "the 505(b)(2) NDA includes new clinical investigations (other than bioavailability

studies) conducted or sponsored by the applicant that were essential to the approval of the application."

A "new clinical investigation" is:

> an investigation in humans the results of which have not been relied on by FDA to demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety for a new patient population and do not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness or safety in a new patient population of a previously approved drug product.

21 C.F.R. § 314.108(a).

"Essential to approval" means, "with regard to an investigation, that there are no other data available that could support approval of the application." Id.

In 2012, the FDA's Center for Drug Evaluation and Research ("CDER") created an Exclusivity Board to "provide oversight and recommendations regarding exclusivity determinations made by the CDER, with a primary focus on clarity and consistency of decisions." (Id. ¶ 68) The Exclusivity Board also "oversees certain exclusivity determinations, including whether and what type of exclusivity should be granted and the proper scope of exclusivity grants." (Id.)

If exclusivity is granted to a drug, the FDA will assign it an exclusivity code that details the scope of the exclusivity. (Id. ¶ 70) The code and its description are listed with the drug product's information in the FDA-maintained publication entitled the *Approved Drug Products with Therapeutic Equivalence Evaluations*. (Id.) Because the cover of the book is orange, it is colloquially referred to as the "Orange Book." (Id.)

D. CDER and Abuse-Deterrent Opioids

In April 2015, CDER published a guide to assist manufacturers wishing to develop opioid drug products with abuse-deterrent properties (the "AD Opioid Guidance"). (Id. ¶ 71) Among other things, the AD Opioid Guidance provides information to drug manufacturers about the FDA's "Physician Labeling Rule." (Id. ¶ 75) Section 9.2 of the Physician Labeling Rule requires that labeling for abuse-deterrent drug products "state the types of abuse that can occur with the drug and the adverse reactions pertinent to them, and must identity particularly susceptible patient populations." (Id.) The AD Opioid Guidance supplies additional detail about Section 9.2, stating that

> labeling language regarding abuse deterrence should describe the product's specific abuse deterrent properties as well as the specific routes of abuse that the product has been developed to deter. For example, a formulation that limits an abuser's ability to crush a tablet and to extract the opioid can be described as limiting manipulation for the purpose of snorting or injection if the data support such a statement.

(Id. ¶ 77)

E. ARYMO

ARYMO, previously discussed in general terms, is an Egalet product for the management of severe, long-term pain. (Id. ¶ 80) It is an abuse-deterrent extended release ("ER") oral morphine formulation to which Egalet applied its proprietary Guardian Technology "for the expected purpose of it becoming an FDA-approved ER morphine drug product with abuse-deterrent labeling for the intranasal, intravenous, and oral routes of abuse." (Id. ¶ 79)

Egalet submitted ARYMO as a 505(b)(2) NDA and selected MS Contin (extended-release morphine tablets) as ARYMO's RLD, thus seeking to establish that its 15mg, 30mg, and 60mg doses were bioequivalent to MS Contin as the same strengths. (Id. ¶ 81) As earlier

discussed, an applicant submitting a 505(b)(2) NDA can rely on clinical studies previously submitted to the FDA in support of another drug (the RLD). (Id. ¶ 82) In this case, Egalet submitted its ARYMO application using clinical studies performed on MS Contin. (Id. ¶ 82) It also conducted its own clinical studies in support of ARYMO's approval, including *in vitro* and human abuse liability studies. (Id. ¶ 83)

ARYMO's abuse-deterrent properties differentiated it from the "vast majority of the ER morphine products prescribed in the U.S." (Id. ¶ 89) In fact, ARYMO's prospects for abuse-deterrent labeling for a trifecta of abuse routes—nasal, intravenous, and oral—was "particularly valuable." (Id. ¶ 90) No product had received FDA-approved abuse-deterrent labeling for all three routes of abuse. (Id.)

F. Inspirion and MorphaBond

Like Egalet, Inspirion is a "pharmaceutical company focused on developing and commercializing products with abuse deterrent features and benefits." (Id. ¶ 92) It applies its patent-protected SentryBond™ technology to deter and frustrate abuse of its products. (Id. ¶ 93)

On November 21, 2014, Inspirion submitted a 505(b)(2) NDA for a product called MorphaBond. (Id. ¶ 89) Like ARYMO, MorphaBond is an extended release, orally administered, morphine product. (Id. ¶ 94) Also like ARYMO, MorphaBond is intended for severe, long-term pain management. (Id. ¶ 95) There are other parallels, as well. (See generally id. ¶¶ 92–118)

Like ARYMO, MorphaBond's application relied on MS Contin as its RLD. (Id. ¶ 97) It conducted *in vitro* and human abuse liability studies. (Id. ¶ 98-99) Its intranasal abuse potential study was "extremely similar in both [] design and scope" to ARYMO's. (Id. ¶ 101)

On October 2, 2015, the FDA approved MorphaBond as the first single-entity ER morphine product with labeling describing intranasal abuse-deterrent properties. (Id. ¶ 103) Inspirion issued a press release three days later announcing the results, and MorphaBond's label, including its intranasal abuse-deterrent labeling, was publicly available during October 2015. (Id. ¶ 104-05)

According to the Amended Complaint, MorphaBond "met all the requirements for receiving exclusivity pursuant to CFR § 314.108(a)." (Id. ¶ 109) The FDA went on to grant MorphaBond a three year period of exclusivity, with its scope defined as "labeling describing the expected reduction of abuse of single-entity extended-release morphine by the intranasal route of administration due to physiochemical properties."[2] (Id. ¶ 114) The exclusivity period for MorphaBond expires on October 2, 2018. (Id. ¶ 116)

As a result of MorphaBond's exclusivity, when ARYMO was approved by the FDA, Egalet was not permitted to market ARYMO as effective at reducing intranasal abuse. (Id. ¶ 229) When the public heard this news, shares of the stock dropped significantly within a matter of days. (Id. ¶ 15)

G. The Alleged False and/or Misleading Statements and Omissions

Plaintiffs point to twenty (20) "events"—each involving one or more statements (or omissions) during the Class Period—in which Defendants made materially false and/or

[2] This sentence, quoted without citation in the Amended Complaint, is at the center of the dispute over Plaintiffs' Motion to Strike (ECF 26).

misleading statements and omissions. Each of the twenty events, as well as the statements or omissions alleged, is described below.[3]

Event #1: November 4, 2015 Earnings Call

During the question-and-answer session of Egalet's conference call on November 4, 2015, a stock analyst from Cantor Fitzgerald asked Defendant Radie to comment on the "Defendants' expectations for ARYMO[']s] label," to which Radie responded that "we would expect that we would have claims for the ability for this product to likely deter [] abuse from an injectability standpoint, from an oral standpoint and from an intranasal standpoint as well." (Id. ¶ 120)

Plaintiffs assert that the statements:

> (1) "misrepresented and failed to disclose adverse facts pertaining to ARMYO[']s] ability to receive the intranasal abuse-deterrent labeling," and
> (2) "were not honestly believed, lacked a reasonable basis, and misrepresented and failed to disclose adverse facts pertaining to the likelihood of ARYMO [] receiving intranasal abuse-deterrent labeling given MorphaBond's exclusivity."

(Id. ¶ 121)

Event #2: December 15, 2015 Press Release

In Egalet's December 15, 2015 press release, it announced that it had filed its 505(b)(2) NDA with the FDA, and that its "submission includes a comprehensive battery of abuse-deterrent studies (Category 1, 2 and 3) which were conducted to support abuse-deterrent label claims for intravenous injection, snorting and oral abuse." (Id. ¶ 171)

[3] Because the PSLRA requires plaintiffs to "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading," the Court is tasked with assessing each of the alleged statements. 15 U.S.C. § 78u–4(b)(1).

Plaintiffs assert that the statements were "false and/or misleading [] and/or omitted to disclose that":

> (1) "ARYMO [] could not and would not receive an intranasal abuse-deterrent label upon approval of [its] 505(b)(2) NDA as MorphaBond's marketing exclusivity for intranasal abuse-deterrent labeling precluded any 'other single-entity extended-release morphine product submitted in [a] 505(b)(2) application [to] be approved for that use,'" and
> (2) "despite the comprehensive battery of abuse-deterrent studies," "the studies would still not allow ARYMO [] to receive FDA approval for the intranasal abuse-deterrent labeling."

(Id. ¶ 172)

Event #3: January 11, 2016 Investor Presentation

On January 11, 2016, Defendant Radie presented a slideshow that Egalet had previously submitted as an attachment to a Form 8-K filed with the SEC. Slides 15 and 17 "touted" the drug's "reductions in oral, intra-nasal, and injection abuse," and slide 18 depicted that it was "potential" for ARYMO to receive an intranasal abuse-deterrent label from the FDA. (Id. ¶¶ 129–30)

Again, according to Plaintiffs, the statements were false, misleading, and/or failed to disclose the existence and effect of MorphaBond's marketing exclusivity on intranasal labeling. (Id. ¶ 131)

Event #4: March 9, 2016 Earnings Call

During a March 9, 2016 conference call to discuss Egalet's 2015 Q4 and 2015 FY results, Defendant Dayno stated that the ARYMO NDA submission had included abuse-deterrent studies "to support abuse-deterrent label claims for intravenous injection, snorting and oral misuse and abuse." (Id. ¶ 134) He also stated that ARYMO is "resistant to particle size reduction, which is the first step in trying to manipulate a product . . . to either snort or inject," and he briefly

described the positive results from one of Egalet's studies assessing the potential for ARYMO's intranasal abuse. (Id.) Plaintiffs also point to Dayno's statement that the FDA's response to the submission was that "no filing review issues were identified." (Id.)

Again, according to Plaintiffs, the statements were false, misleading, and/or failed to disclose the existence and effect of MorphaBond's marketing exclusivity on intranasal labeling.[4] (Id. ¶ 135)

Event #5: 2015 Form 10-K

Egalet's 2015 Form 10-K, signed and certified by Defendants Radie and Musial, stated that ARYMO's NDA submission included a battery of abuse-deterrent studies "which were conducted to support [abuse-deterrent] label claims for intravenous injection, snorting and oral abuse." (Id. ¶ 138) It also briefly summarized the positive results from one of Egalet's submitted studies assessing the potential for ARYMO's intranasal abuse. (Id. ¶ 139) The 10-K also discussed the "Risks Related to Our Business and Strategy," but was "silent as to any effect that MorphaBond's approval had on the intranasal abuse-deterrent labeling sought for ARYMO." (Id. ¶ 142) Instead, it only provided one example of how Egalet's business prospects could be affected by an exclusivity period for a competing drug; the example pertained to Egalet-002, not ARYMO:

> Furthermore, if the FDA approves a competitor's 505(b)(2) application for a drug candidate before our application for a similar drug candidate, and grants the competitor a period of exclusivity, the FDA may take the position that it cannot approve our NDA for a similar drug candidate. For example, we believe that several competitors are developing extended-release oxycodone products, and if the FDA approves a competitor's 505(b)(2) application for

[4] This sentence is incorporated by reference into the end of each of the twenty subsections in this section.

> an extended release oxycodone product and grants exclusivity before our NDA for Egalet-002 is filed and approved, we could be subject to a delay that would dramatically reduce our expected market potential for Egalet-002. Additionally, even if our 505(b)(2) application for Egalet-002 is approved first, we may still be subject to competition from other oxycodone products, including approved products or other approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

(Id. ¶ 142)

Event #6: April 5, 2016 Investor Presentation

Plaintiffs also point to Egalet's April 5, 2016 Form 8-K, which attached an investor presentation. (Id. ¶ 145) Slides 9 and 11 "touted" the drug's "reductions in oral, intra-nasal, and injection abuse," and slide 12 depicted that it was "potential" for ARYMO to receive an intranasal abuse-deterrent label from the FDA. (Id. ¶¶ 146–47)

Event #7: May 10, 2016 Earnings Call

During Egalet's May 10, 2016 conference call, Defendant Radie discussed Egalet's preparation for ARMYO's FDA advisory committee meeting, stating "[w]e believe the novelty of our guarding [sic] technology and the strength of our abuse-deterrent data generated from our category one, two and three studies will support a differentiated label for ARYMO." (Id. ¶ 151) Then, during the question-and-answer session, Radie stated:

> We've met all the primary and key secondary endpoints from all of the various category one, two and three abuse-deterrent studies that we conducted. So that gives us a tremendous amount of confidence and the FDA showed some consistency in their review is that they want to see that these products meet the primary endpoint in the various studies that are done and key secondary endpoints as per the guidance that they spent a lot of developing, getting a lot of external expertise to develop those guidance and I think that that's what we're going to see is the sponsors regularly being held to those standards and we believe that ARYMO meet those standards put forth in the guidance.

(Id. ¶ 152)

Again, according to Plaintiffs, the statements were false, misleading, and/or failed to disclose the existence and effect of MorphaBond's marketing exclusivity on intranasal labeling. (Id. ¶ 153) Moreover, to the extent that any of the statements can be considered statements of opinion, Plaintiffs assert that they "were not honestly believed, lacked a reasonable basis, and misrepresented and failed to disclose adverse facts pertaining to the likelihood of ARYMO [] receiving intranasal abuse-deterrent labeling," given MorphaBond's exclusivity. (Id.)

Event #8: May 11, 2016 Conference Presentation

During Egalet's presentation at the Bank of America/Merrill Lynch Health Care Conference on May 11, 2016, the company utilized a slideshow they had previously filed as an attachment to a Form 8-K. (Id. ¶ 155) Slides 9 and 10 "touted" the drug's "reductions in oral, intra-nasal, and injection abuse," and slide 11 depicted that it was "potential" for ARYMO to receive an intranasal abuse-deterrent label from the FDA. (Id. ¶¶ 156–57)

Event #9: May 12, 2016 Press Release

Egalet issued a press release on May 12, 2016 announcing that it had presented data at the American Pain Society's Annual Meeting that demonstrated that ARYMO "significantly lowered intranasal abuse potential as compared to MS Contin (ARYMO['s] RLD)." (Id. ¶ 160) The press release also described the positive results from one of Egalet's studies assessing ARYMO's ability to deter intranasal abuse. (Id. ¶ 161)

Event #10: June 21, 2016 Form 8-K

Egalet filed a Form 8-K on June 21, 2016 that contained an investor presentation. (Id. ¶ 164) Slides 27 and 28 "touted" the drug's "reductions in oral, intra-nasal, and injection abuse,"

and slide 12 depicted that it was "potential" for ARYMO to receive an intranasal abuse-deterrent label from the FDA. (Id. ¶¶ 165–66)

Event #11: June 28, 2016 Press Release

Egalet issued a press release on June 28, 2016, announcing that the FDA had scheduled a joint meeting for August 4, 2016 with the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee (the "Joint Advisory Committee") to review ARYMO (the "Joint Meeting"). (Id. ¶ 169) The press release indicated that ARYMO's NDA included studies conducted to support abuse-deterrent label claims for intravenous injection, snorting, and oral routes of misuse and abuse. (Id. ¶ 171)

Event #12: August 4, 2016 Press Release

On August 4, 2016, the FDA held its Joint Meeting "to discuss whether the clinical data supported approvability and abuse-deterrent labeling for ARYMO." (Id. ¶ 174) The Joint Advisory Committee tasked with assessing the approvability and abuse-deterrent labeling language for ARYMO described its first task as determining whether there was "sufficient data to support a finding that [ARYMO] has properties that can be expected to deter abuse, commenting on support for abuse-deterrent effects for each of the three possible routes of abuse": oral, intranasal, and intravenous. (Id. ¶ 177)

Although the Joint Advisory Committee members "were not asked to evaluate or review whether any FDA-granted exclusivities or patents existed that could affect ARYMO[']s approval or labeling," the Joint Advisory Committee voted to recommend to the FDA that the scientific data included with ARYMO's NDA submission supported abuse-deterrent labeling for all three routes of abuse: oral, intranasal, and intravenous. (Id. ¶¶ 178, 183)

Later on August 4, 2016, Egalet issued a press release announcing the results of the Joint Meeting. (Id. ¶ 182) That press release stated, in relevant part:

> [The Joint Advisory Committee] voted 18 to 1 to recommend approval of ARYMO.
> …
> [The Joint Advisory Committee] also voted:
> - 16 to 3 that if approved, ARYMO [] should be labeled as an abuse-deterrent product by the oral route of abuse;
> - 18 to 1 that if approved, ARYMO [] should be labeled as an abuse-deterrent product by the nasal route of abuse; and
> - 18 to 1 that if approved, ARYMO [] should be labeled as an abuse-deterrent product by the intravenous route of abuse.
>
> …
> "The Committees' support of ARYMO [] labeling as an abuse-deterrent product by the intravenous, nasal and oral routes of abuse is an important step forward in the development of this product candidate," said Bob Radie.
> …
> Based on the committees' votes, Egalet anticipates, if approved, the label for ARYMO [] will describe the product's abuse-deterrent properties that are expected to reduce, but not totally prevent, abuse of the drug when the tablets are manipulated. The FDA is not abound by the recommendations of its advisory committees . . . .

(Id. ¶ 183)

Event #13: August 4, 2016 Earnings Call

Later on August 4, 2016, Egalet held a conference call, during which Defendant Radie summarized the Joint Advisory Committee's votes, and stated that "[w]e are encouraged by the outcome of today's [Joint Meeting], and support for labeling ARYMO [] as an abuse deterrent product by the intravenous, nasal and oral routes of abuse." (Id. ¶ 186–187) Radie went on to say that, "[i]f approved, this could be the broadest label for an abuse deterrent extended release morphine product candidate," and that "[i]t is our hope and expectation that we will achieve

abuse deterrent claims in the label for the intravenous routes, oral routes and intranasal routes of abuse." (Id. ¶¶ 188–89)

Radie explained that his "statement about this . . . revolves around the comparisons of the labels for the other two currently approved abuse deterrent extended release morphine products being Embeda and MorphaBond." (Id. ¶ 189) He also detailed the claims that Embeda and MorphaBond have in terms of abuse deterrence: "Embeda has claims for intranasal and oral abuse [] and MorphaBond has an intranasal and IV claim," while "if successful we would expect to be able to achieve all three of those claims in our label [intranasal, oral, and intravenous]." (Id.)

Event #14: August 5, 2016 Form 10-Q

Egalet's August 5, 2016 Form 10-Q, reporting its 2Q2016 results summarized the results of the Joint Meeting, and disclosed the risk that "[i]f we fail to obtain the necessary regulatory approvals, or if such approvals are limited, we will not be able to commercialize our product candidates, and we will not generate product revenues." (Id. ¶ 196) More specifically, the 10-Q disclosed that "the FDA is not bound by the Advisory Committees' recommendations as it continues its review of ARYMO []. As a result, there is a risk that the FDA could determine not to approve ARYMO [], or to approve ARYMO [], but without abuse-deterrent labeling." (Id. ¶ 196)

Event #15: August 26, 2016 Form 8-K

Egalet filed a Form 8-K on August 26, 2016 that contained an investor presentation. (Id. ¶ 200) Slide 8 "touted" the drug's "reductions in oral, intra-nasal, and injection abuse," and slide 9 depicted that it was "potential" for ARYMO to receive an intranasal abuse-deterrent label from the FDA. (Id. ¶¶ 201–02)

Event #16: October 13, 2016 Press Release

Egalet issued a press release on October 13, 2016 stating that the FDA would not meet its previous goal date for determining whether to approve ARYMO. (Id. ¶ 205) In the press release, Egalet again summarized the results of the Joint Meeting, and stated that the FDA "confirmed that not additional scientific information or data is needed for our application." (Id. ¶ 206)

Event #17: November 4, 2016 Earnings Call

Egalet held a conference call on November 4, 2016, stating, in relevant part, "[w]e were encouraged by the outcome of the FDA advisory committee meeting and support for labeling ARYMO [] as an abuse deterrent product." (Id. ¶ 212)

Event #18: November 14, 2016 Form 8-K

Egalet filed a Form 8-K on November 14, 2016 that contained an investor presentation. Slide 8 "touted" the drug's "reductions in oral, intra-nasal, and injection abuse." (Id. ¶ 216)

Event #19: November 15, 2016 Conference Presentation

Defendant Radie presented on November 15, 2016 at the Stifel Healthcare Conference. (Id. ¶ 219) Plaintiffs highlight the following statements:

> [A]t that advisory committee meeting we received very strong support 18 to 1 vote in favor of approval of ARYMO with abuse-deterrent labeling, and then similarly they asked three other questions in addition to approval of the advisors, they asked, does it—does the data suggest it would deter abuse the intravenous, the nasal and the oral route, and all of those votes were overwhelmingly positive in favor of ARYMO.
> …
> It's important to note that they did not request any additional data from the company, and additional scientific information and instead basically led us to recognize if there were a patent approved abuse-deterrent products [sic] missing their [goal] date

> and that this product was likely to meet that patent just based on the complexities of the FDA's process to approve opioids.
> …
> [W]e know from their statement [] that they're actively working on our label, which we believe are all very positive signs.

(Id. ¶ 220)

Event #20: January 9, 2017 Conference Call

On January 9, 2017 at 2:51 p.m. ET, Egalet announced the FDA's approval of ARYMO's NDA. (Id. ¶ 223) That same day, the FDA announced its approval of ARYMO but also announced that ARYMO would not receive intranasal abuse labeling because MorphaBond already possessed marketing exclusivity for "the expected reduction of abuse of single-entity extended-release morphine by the intranasal route." (Id. ¶ 224)

Plaintiffs highlight a question posed to Defendant Radie at a conference call held later that same day: "[T]he exclusivity around the intranasal data, was that a surprise to you?" (Id. ¶ 230) In response, Radie stated, "we had considered it, but we couldn't predict any definitive outcome based on previous exclusivity findings in this class." (Id.)

H. Egalet's Stock Price Falls

In response to the news disclosed on January 9, 2017, Egalet's stock price dropped from a closing price of $8.38 on January 9, 2017, to a closing price of $6.52 per share on January 10, 2017, a stock drop of approximately 22%. (Id. ¶ 231) The next day, the stock price further dropped, closing at $5.99 per share. (Id.) By May 31, 2017, the stock price had dropped to a low of $2.03. (Id.)

I. Relevant Post-Class Period Statements

In support of their allegations, Plaintiffs include in their Amended Complaint several post-Class Period statements. (Id. ¶¶ 232–239) Several of the statements were made by stock

analysts outside Egalet. (Id. ¶¶ 233–34) For example, a Cantor Fitzgerald analyst stated that "our enthusiasm following the approval to ARYMO [] this afternoon was tempered as the label, which we expected to include abuse-deterrent [] claims in oral, intranasal, and IV routes of abuse, only included IV." (Id. ¶ 233)

However, some of the statements appear in Egalet's financial statements. For example, Plaintiffs highlight that Egalet's Form 10-K filed on March 13, 2017 disclosed new risks that Egalet had not previously mentioned, such as that "the FDA may not approve the labeling claims, including claims regarding abuse deterrence, that we believe are necessary or desirable for the successful commercialization of our products and product candidates." (Id. ¶ 237) Another risk that had previously not been included in Egalet's financial statements was that, "if the FDA approves a competitor's 505(b)(2) application for a drug candidate before our application for a similar drug candidate, and grants the competitor a period of exclusivity, the FDA may take the position that it cannot approve our FDA . . . or that our label cannot reflect certain claims." (Id. ¶ 239)

IV. Motion to Strike

Defendants' Motion to Dismiss includes various attachments as exhibits. In response, Plaintiffs filed a Motion to Strike Exhibit 1 (to the Motion to Dismiss), or in the alternative, to treat Defendants' Motion to Dismiss as a motion for summary judgment. Exhibit 1 to Defendants' Motion to Dismiss is a memorandum, dated November 16, 2016 and signed November 29, 2016, written by the FDA's CDER Exclusivity Board regarding the "Scope of 3-Year Exclusivity for MorphaBond." (MTD, Ex. 1, the "CDER Memo")

A. Parties' Contentions

In the Motion to Dismiss, Defendants assert that the Court can consider the CDER Memo "because it is explicitly relied upon in the [Amended Complaint] and integral to Plaintiffs' claims." (MTD, at 1, n.1) Defendants indicate that paragraph 114 of the Amended Complaint quotes from the CDER Memo. (Id.)

Plaintiffs contend that this Court should strike Exhibit 1, and all factual assertions made by Defendants in reliance on it, because:

> (1) "the Complaint does not rely upon or even reference the CDER Memo a single time"; and
> (2) "the CDER Memo is not integral to Plaintiffs' claims which are based on Defendants' public misrepresentations regarding their efforts to secure FDA approval of a broad label for ARYMO [] covering intranasal abuse deterrence while failing to disclose a risk to the approvability of that label."

(MTS, at 2)

Plaintiffs specifically refute Defendants contention that the CDER Memo is quoted in Paragraph 114 of the Amended Complaint, and aver that "the CDER Memo is not quoted, cited, or referenced anywhere else in the Amended Complaint." (Id., at 6) Instead, Plaintiffs assert, Paragraph 114 "refers to the exclusivity code given to MorphaBond in the Orange Book." (Id.)

Moreover, Plaintiffs state, because Defendants rely on the CDER Memo for the truth of the information contained within it, the Court should disregard Defendants' factual assertions based on the CDER Memo.[5] (Id., at 7)

[5] Plaintiffs distinguish between considering documents "for the truth of the matter asserted," and "for the limited purpose of showing that particular statement was made by a particular person." Plaintiffs do not dispute that it is "appropriate for the Court to consider, and take judicial notice of" the existence and publication date of the CDER Memo. (See MTS Reply, at 3)

In their Response, Defendants contend that Paragraph 114 of the Amended Complaint "contains the exact language found in the conclusion of the Memo, in quotation marks, without any attribution to another source." (MTS Response, at 1) Thus, they say it is "relied upon" by Plaintiffs in making their claims and should be considered by the Court. (Id.)

Defendants also contend that the CDER Memo is "integral to" the Amended Complaint and may be considered by the Court even if it were not cited in the Amended Complaint. (Id.) Defendants characterize Plaintiffs' description of the case as "being about what Defendants supposedly knew about the risk that the FDA would not approve the labeling Egalet had requested for ARYMO [] because of MorphaBond's exclusivity." (Id.) Because the CDER Memo—published in November of 2016 (after the Class Period had ended)—appears to demonstrate that the scope of MorphaBond's exclusivity was undecided prior to that point, Defendants assert that the CDER Memo specifically addresses what Defendants could have known (and/or could not have known) during the Class Period. (Id.) Moreover, Defendants contend, the CDER Memo "sets forth the FDA's reasoning underlying its decision about the scope of exclusivity to which MorphaBond was entitled," thus demonstrating the "nature of the risk" that Defendants allegedly should have disclosed. (Id.)

Lastly, Defendants assert that the Court "may judicially notice [the CDER Memo] as a public record." (Id.) Even if the CDER Memo were not integral to the Amended Complaint (which Defendants do not concede), they contend that the Court could take "judicial notice of the

date of the Memo's publication," and this fact alone would be sufficient to dismiss Plaintiffs' claims.[6] (Id. at 2)

In their Reply, Plaintiffs assert that the language of Paragraph 114 of the Amended Complaint was not drawn from the CDER Memo, but rather from MorphaBond's exclusivity code, as expressed in the FDA's Orange Book (which also includes the exact language quoted in Paragraph 114). (MTS Reply, at 2) Thus, they contend, the CDER Memo was not "explicitly relied upon" in the Amended Complaint. (Id., at 7)

Plaintiffs also dispute Defendants characterization of the CDER Memo as "integral to" their claims. (Id., at 2) Plaintiffs highlight that they do not claim any statement in the CDER Memo was fraudulent, do not rely upon it to show any element of their claims, and do not mention or cite it for any proposition. (Id., at 6)

Lastly, Plaintiffs contend that even if the Court were to take judicial notice of the CDER Memo, the Court should strike any assertions contained in Defendants' Motion to Dismiss that rely on the CDER Memo for the truth of the matter asserted, i.e., to "demonstrate that Defendants could not have known the scope of Morpha[B]ond's exclusivity." (Id., at 7–8)

B. Legal Standard

In general, a district court considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6) "may not consider matters extraneous to the pleadings" without converting the motion into one for summary judgment. In re Burlington Coat Factory Sec. Litg., 114 F.3d 1410, 1426 (3d Cir.

[6] Here, Defendants' Motion to Strike treads on ground that this Court plans to address later, within the context of the Motion to Dismiss. For present purposes, it suffices to say that in their Reply brief, Plaintiffs dispute Defendants' contention.

1997). However, there are at least three exceptions to this general rule. Courts may also consider:

(1) Exhibits attached to the complaint;
(2) Matters of public record; and
(3) Undisputedly authentic documents integral to or explicitly relied upon in the complaint.

Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014)

In this case, Exhibit 1 was not attached to Plaintiffs' Amended Complaint, but rather Defendants' Motion to Dismiss. Thus, only the latter two exceptions are relevant here.

C. Public Records

It is undeniable that documents qualifying as public records may be judicially noticed by courts. The Third Circuit has expressed its approval of district courts considering public records, ranging from SEC filings, id., and published reports of administrative bodies, City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 259 (3d Cir. 1998), to criminal case dispositions and decision letters of government agencies, Pension Ben. Guar. Corp. v. White Consol. Industries, Inc., 998 F.2d 1192, 1197 (3d. Cir. 1993). The Supreme Court has also expressed its approval of courts considering "other sources" beyond the complaint, such as "matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

A public record is not simply one that is accessible to the public, but rather one to which "the public ha[s] unqualified access." Pension Ben., 998 F.2d 1192, 1997 (3d Cir. 1993). Thus, it is not sufficient that the public can access a written exchange between a regulator and a company it regulates through a Freedom of Information Act request. Id.

Although the Third Circuit has not considered the specific question of whether a court may consider FDA records on a Rule 12(b)(6) motion, other courts in this district have decided

they may properly do so, including reports published on the FDA website. See, e.g., In re Viropharma, Inc. Sec. Litig., No. 02-cv-1627, 2003 WL 1824914, at *1 (E.D. Pa. Apr. 7, 2003); In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003); Starks v. Coloplast Corp., No. 13-cv-3872, 2014 WL 617130, at *2 (E.D. Pa. Feb. 18, 2014); see also Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011). In the present case, the public has unqualified access to the CDER Memo, which is accessible to the public via the FDA website.[7] Thus, this Court will take judicial notice of the CDER Memo.[8]

The next issue for the Court to decide is for what purposes the CDER Memo may be judicially noticed. Fed. R. Evid. 201(b)(2) allows courts to take judicial notice of any "fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." In prior cases in this circuit, courts have taken "judicial notice of the veracity of" FDA website documents, Scanlon v. Medtronic Sofamor Danek USA Inc., 61 F.Supp.3d 403, 413 n. 16, to, among other things, illustrate approval of medical devices, see, e.g., Starks, 2014 WL 617130, at *4. "Such notice serves only to indicate what was in the public realm at the time, not whether the contents of those documents are true." U.S. ex rel. Spay v. CVS Caremark Corp., 913 F.Supp.2d 125, 139-140 (citing Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 401 n. 15 (3d Cir. 2006).

The same can be done here. The accuracy of the CDER Memo "cannot reasonably be questioned". Fed. R. Evid. 201(b)(2). Judicial notice of the Memo serves to illustrate that the

[7]https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM540646.pdf.

[8] Plaintiffs appear to impliedly concede this point in their briefing. See MTS Reply at 7.

FDA wrote its decision as to the scope of the MorphaBond's exclusivity on November 16, 2016 and signed it on November 29, 2016.[9] It "indicate[s] what was in the public realm at the time," and it also indicates what was not in the public realm at the time (i.e., a final agency determination as to the scope of MorphaBond's marketing exclusivity on intranasal abuse-deterrent claims in morphine pharmaceuticals of its kind). U.S. ex rel. Spay, 913 F.Supp.2d at 139.

D. Integral or Relied-Upon Documents

Courts may consider documents "integral to or explicitly relied upon in the complaint . . . without converting the motion to dismiss into one for summary judgment." Schmidt, 770 F.3d at 249 (citing In re Burlington, 114 F.3d at 1426). In In re Burlington, 114 F.3d 1410, a seminal Third Circuit securities case, the Court explained that "[t]he rationale underlying this exception is that the primary problem raised by looking to documents outside the complaint—lack of notice to the plaintiff—is dissipated where plaintiff has actual notice . . . and has relied upon these documents in framing the complaint." Id. at 1426 (internal citation omitted). Much like the present case, the complaint in In re Burlington did "not explicitly refer to or cite" the challenged exhibit. Id. Nonetheless, the Court considered the exhibit, deciding that the critical inquiry was "not merely whether the extrinsic document was explicitly cited," but rather "whether the claims in the complaint are 'based' on [the] extrinsic document." Id. Ultimately, the Court explained, "Plaintiffs cannot prevent a court from looking at the texts of the documents on which its claim is based by failing to attach or explicitly cite them."

[9] Note that, as detailed in the below subsection, *supra*, this Court may also fully consider the CDER Memo as a document integral to, and relied upon by, the Amended Complaint. Nonetheless, the Court need not go beyond judicially noticing the Memo to grant the Motion to Dismiss.

However, it is not enough that the complaint rely upon the extrinsic document. The document must also be "undisputedly authentic." In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357, 368 n. 9 (3d Cir. 1993).

In this case, it is clear that the CDER Memo is a document that this Court may properly consider. For reasons discussed earlier with respect to the question of judicial notice, *supra*, the CDER Memo is indisputably authentic—so much so that Plaintiffs do not contest its authenticity. See, e.g., Pryor v. Nat'l Collegiate Athletic Ass'n., 288 F.3d 548, 560 (3d Cir. 2002) ("[D]ocuments whose contents are alleged in the complaint and whose authenticity no party questions, but which are not physically attached to the pleading, may be considered." (quotation omitted))

Moreover, the CDER Memo was both explicitly relied upon and integral to the Amended Complaint. The CDER Memo contains the exact language found in the conclusion of the Memo, in quotation marks, without any attribution to a source. Compare CAC ¶ 114 ("Predictably, the FDA defined MorphaBond's scope of exclusivity as '***labeling describing the expected reduction of abuse of single-entity extended-release morphine by the intranasal rout [sic] of administration due to physiochemical properties***.") with CDER Memo, at 2 ("The Board . . . concludes that the scope of MorphaBond's exclusivity is ***labeling describing the expected reduction of abuse of single-entity extended-release morphine by the intranasal route of administration due to physiochemical properties***.") (emphases added).[10]

[10] Plaintiffs claim that the source of the language is the FDA's Orange Book, where FDA's exclusivity decisions are recorded. What they fail to mention is that the Orange Book was updated after the publication of, and as a result of, the CDER Memo, which is the source of the language reflecting the scope of MorphaBond's exclusivity.

Notably, the primary claim—repeated throughout Plaintiff's Amended Complaint—is that Defendants failed to disclose that ARYMO "could not and would not receive an intranasal abuse-deterrent label" because it was precluded by "MorphaBond's marketing exclusivity for intranasal abuse-deterrent labeling." (See CAC ¶¶ 121, 125, 131, 135, 140, 143, 153, 162, 172, 184, 198, 207). MorphaBond's marketing exclusivity began, according to Plaintiffs, "at the time the FDA approved MorphaBond's 505(b)(2) NDA," on October 2, 2015. (MTS Reply, at 8) However, its marketing exclusivity for the specific type of intranasal abuse-deterrent labeling at issue in this case was not yet determined on that date. Instead, it was not until November 29, 2016 that the FDA published the CDER Memo detailing the scope of MorphaBond's exclusivity (with such exclusivity made retroactive to October 2, 2015). (See CDER Memo) In other words, if not for the CDER Memo, the FDA would not have decided that MorphaBond has marketing exclusivity for intranasal abuse-deterrent labeling for drugs of this kind. That fact alone demonstrates that the CDER Memo is integral to the Amended Complaint. It is the final, official FDA document establishing the scope of exclusivity specifically at issue in this case.

V. Motion to Dismiss

Having decided that the CDER Memo may properly be considered at this stage of the litigation, the Court now turns to the underlying motion at issue: Defendants' Motion to Dismiss the Amended Complaint.

A. Parties' Contentions

In their Motion to Dismiss, Defendants make four primary arguments:

(1) Because the CDER Memo demonstrates that the scope of MorphaBond's exclusivity had not been established during the Class Period, none of the allegedly false or misleading statements were, in fact, false;

(2) Because the Amended Complaint's allegations that Defendants knew or should have known of MorphaBond's exclusivity are based on publicly available information, any omission of this information is immaterial (i.e., "truth on the market" defense);

(3) Because many of Defendants' statements were forward-looking, Defendants are shielded from liability for those statements under the PSLRA's safe harbor provision; and

(4) Because Defendants' alleged motives are legally insufficient, and the Amended Complaint does not demonstrate actual knowledge, there is no scienter.

In Response, Plaintiffs assert that:

(1) Because the false or misleading statements were made misleading as a result of a failure to disclose the substantial risk that MorphaBond's exclusivity would include abuse-deterrent labeling for intranasal abuse, the CDER Memo does not change the false or misleading nature of Defendants' statements;

(2) Because the "truth on the market" defense has a high burden, it is not an appropriate basis for dismissing the complaint in most circumstances, including in this case, where the stock price dropped once the relevant information was revealed;

(3) Because many of Defendants' misstatements were not forward-looking, were made with actual knowledge that they were misleading and false, were not accompanied by meaningful cautionary language, and, if believed, were not reasonable, the PSLRA's safe harbor provision does not shield Defendant's statements from liability; and

(4) Because the Amended Complaint demonstrates Defendants' knowledge of the undisclosed risk and the relevant regulatory landscape, the Amended Complaint sufficiently alleges scienter. It also adequately alleges motive and opportunity as a means of demonstrating scienter.

B. Legal Standard

In considering a motion to dismiss under Rule 12(b)(6), "we accept all factual allegations as true [and] construe the complaint in the light most favorable to the plaintiff." Warren Gen. Hosp. v. Amgen, Inc., 643 F.3d 77, 84 (3d Cir. 2011) (internal quotation marks and citations omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter,

accepted as true, to 'state a claim for relief that is plausible on its fact.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, (2007)).

Fed. R. Civ. P. 9(b) imposes an additional pleading requirement "[i]n all averments of fraud or mistake," obliging claimants in such cases that "the circumstances constituting fraud or mistake shall be stated with particularity." This particularity requirement has been "rigorously applied" in securities fraud cases. In re Burlington, 114 F.3d at 1417. At a minimum, plaintiffs should be able to name the "who, what, when, where and how" of the fraud. Id. at 1422. Rule 9(b) gives defendants "notice of the claims against them, provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements." Id. at 1418.

C. Analysis

In this case, Plaintiff's seek relief under § 10(b) of the Securities Exchange Act. "Section 10(b) prohibits the 'use or employ, in connection with the purchase or sale of any security, . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe ...." In re Ikon Office Solutions, Inc., 277 F.3d 658, 666 (3d Cir. 2002) (quoting 15 U.S.C. §78j(b)). Rule 10b–5, in turn, created a private right of action for investors harmed by materially false or misleading statements to enforce §10(b), and it "makes it unlawful for any person '[t]o make any untrue statement of a material fact or to omit to state a material fact necessary to make the statements made in the light of the circumstances under which they were made, not misleading ... in connection with the purchase or sale of any security.' " Id. (quoting 17 C.F.R. §240.10b–5(b)).

To prevail on their claim under §10(b), Plaintiffs must prove:

(1) A material misrepresentation or omission by Defendants;

(2) Scienter;
(3) A connection between the misrepresentation or omission and the purchase or sale of a security;
(4) Reliance upon the misrepresentation or omission;
(5) Economic loss; and
(6) Loss causation.

Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37-38 (2011).

Defendants' Motion to Dismiss focuses on the first and second elements above, but also relies on the PSLRA's Safe Harbor Provision, 15 U.S.C. §78u–5(c), which shields Defendants against § 10(b) liability for "forward-looking" statements accompanied by "meaningful cautionary language."

Thus, the Court will (1) assess whether the Safe Harbor Provision insulates Defendants against § 10(b) liability; and then determine whether Plaintiffs have adequately alleged (2) a material misrepresentation or omission by Defendants, and (3) Defendants' scienter.

(1) Safe Harbor

The PSLRA's Safe Harbor Provision provides that:

> [A] person ... shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that—
>
> (A) the forward-looking statement is—
>
> (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or
>
> (ii) immaterial; or
>
> (B) the plaintiff fails to prove that the forward-looking statement—
>
> (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
>
> (ii) if made by a business entity; was—

> (I) made by or with the approval of an executive officer of that entity; and
>
> (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

15 U.S.C. § 78u–5(c)(1). See Institutional Inv'rs Grp. v. Avaya, Inc., 564 F.3d 242, 254 (3d Cir. 2009).

Thus, the PSLRA's Safe Harbor shields a defendant from liability where the challenged forward-looking statement is "identified as forward-looking,"[11] and "accompanied by meaningful cautionary statements." 15 U.S.C. § 78u–5(c)(1).[12]

Defendants do not raise the Safe Harbor defense with respect to all of the alleged misstatements or omissions. Instead, they assert that it applies to the following challenged statements (the "Challenged Forward-Looking Statements"):

- CAC ¶ 120: "And so we would expect that we would have claims for the ability for this product to likely deter-abuse from an injectability standpoint, from an oral standpoint and from an intranasal standpoint as well.";
- CAC ¶¶ 129, 146, 156: Slides entitled "ARYMO ER: AD Morphine Could be on Market in '16*";
- CAC ¶¶ 130, 147, 157, 166: Slides entitled "Potential ARYMO ER Label Vs. Competition";
- CAC ¶ 151: "We believe the novelty of our guardi[an] technology and the strength of our abuse-deterrent data generated from our category one, two and three studies will support a differentiated label for ARYMO ER.";
- CAC ¶ 152: "We've met all the primary and key secondary endpoints from all of the various category one, two and three abuse-deterrent studies that we conducted. So that gives us a tremendous amount of confidence and the FDA showed some consistency in

[11] Defendants noted in each of their conference calls, press releases, and presentations that forward-looking statements were contained therein. Plaintiffs do not contest this point. See Avaya, 564 F.3d at 256 n. 22.

[12] The statute also mandates that, "on any motion to dismiss" based on the Safe Harbor Provision, "the court shall consider any statements cited in the complaint and any cautionary statement accompanying the forward-looking statement, which are not subject to material dispute, cited by the defendant." 15 U.S.C. § 78u–5(e).

their review is that they want to see that these products meet the primary endpoint in the various studies that are done and key secondary endpoints as per the guidance that they spent a lot of [time] developing, getting a lot of external expertise to develop those guidance and I think that that's what we're going to see is the sponsors regularly being held to those standards and we believe that ARYMO meet[s] those standards put forth in the guidance.";

- CAC ¶ 165: Slide entitled "ARYMO ER Could be on Market by Year-End*";
- CAC ¶ 183: "Based on the committees' votes, Egalet anticipates, if approved, the label for ARYMO ER will describe the product's abuse-deterrent properties that are expected to reduce, but not totally prevent, abuse of the drug when the tablets are manipulated."
- CAC ¶ 188: "We are encouraged by the panel's support for ARYMO as an abuse deterrent morphine, and we are encouraged by their support for all three abuse deterrent claims of oral, intranasal, and IV. If approved, this would be the broadest label for an abuse deterrent extended release morphine product candidate."
- CAC ¶ 189: "It is our hope and expectation that we will achieve abuse deterrent claims in the label for the intravenous routes, oral routes and intranasal routes of abuse. . . . So if successful we would expect to be able to achieve all three of those claims in our label."

MTD, at 24–25.

Defendants made the Challenged Forward-Looking Statements in earnings calls on November 4, 2015, May 10, 2016, and August 4, 2016; investor presentations filed as attachments to Forms 8-K on January 11, 2016, April 5, 2016, May 11, 2016, and June 21, 2016, and a press release on August 4, 2016. See *supra*, Events ## 1, 2, 6–8, 10, 12–13.

Plaintiffs contend that "[m]any of the misleading statements identified in the Complaint are not forward-looking," and, with respect to those statements that "potentially may be deemed forward-looking," those statements were "inextricably intertwined with statements of present or history fact [and/or] were not accompanied by meaningful cautionary language." MTD Response, at 30.[13] The Court must therefore consider whether the Challenged Forward-Looking

[13] Plaintiffs also contend that the Safe Harbor does not apply because the statements were made with actual knowledge that the statements were false and misleading. However, it is settled law

Statements constitute "forward-looking statements," and whether they are "accompanied by meaningful cautionary language."

i. Forward-Looking Statement

The term "forward-looking statement" is defined in the Safe Harbor statute, and it includes, "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer," as well as "any statement of the assumptions underlying or relating to any" forward-looking statement. 15 U.S.C. § 78u–5(i)(1)(B),(D). As Defendants point out, courts in this circuit have repeatedly found "that statements regarding the likelihood and timing of FDA approval for a drug and the reasons for management's beliefs that such approval will occur fall under the statutory definition of 'forward-looking.'" (MTD, at 23–24) See, e.g., Bauer v. Eagle Pharm., Inc., No. 16-cv-3091, 2017 WL 2213147, at *9 (D.N.J. May 19, 2017) (Statements such as "[w]e expect to launch," and "if approved, [we] intend to launch our [product] the following day," which "relat[e] to anticipated FDA approval of the NDA are forward-looking statements protected by the Safe

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in the Third Circuit (and many other Circuits) that such knowledge is not relevant to a Safe Harbor inquiry based on 15 U.S.C. § 78u–5(c)(1)(A):

> The provisions of the safe harbor under § 78u–5(c)(1) are disjunctive; they immunize any forward-looking statement provided that **either** it is "accompanied by meaningful cautionary statements," *id*. § 78u–5(c)(1)(A), **or** "the plaintiff fails to prove the forward-looking statement ... was made with actual knowledge ... that the statement was false or misleading," *id*. § 78u–5(c)(1)(B). Thus, where a future-looking statement is accompanied by sufficient cautions, then the state of mind of the individual making the statement is irrelevant, and the statement is not actionable regardless of the plaintiff's showing of scienter.

OFI Asset Mgmt. v. Cooper Tire & Rubber, 834 F.3d 481, 502 (3d Cir. 2016) (collecting cases).

Harbor Provision)); In re Discovery Labs. Sec. Litig., No. 06-cv-1820, 2006 WL 3227767, at *4 (E.D. Pa. Nov. 1, 2006) (Statements such as "[w]e intend to use the results from [successful clinical] trials to form the basis for a new drug application (NDA) with the [FDA]," and "[the company] now is focusing on preparing for the commercialization of [the product] for Respiratory Distress Syndrome (RDS), if approved," are forward-looking).

Plaintiffs note that "a mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present." Institutional Inv'rs Grp. v. Avaya, Inc., 564 F.3d 242, 255 (3d Cir. 2009) (citation omitted). However, just as the Court in Bauer, *supra*, found that "statements anticipating FDA approval are not transformed into mixed present/future statements by virtue of references" to present events, see also Avaya, 564 F.3d at 255, statements about the likelihood of FDA approval are not mixed present/future statements here either. For example, statements such as, "[i]t is our hope and expectation that we will achieve abuse deterrent claims in the label for the intravenous routes, oral routes and intranasal routes of abuse," CAC ¶ 189, are clearly forward-looking, despite the fact that they express Egalet's presently-existing "hope and expectation" of future projections. See Avaya, 564 F.3d at 255 (finding that statements such as "we are on track to meet our goals for the year" are forward-looking because the present tense component, "when read in context, cannot meaningfully be distinguished from the future projection of which [it is] a part").

ii. Meaningful Cautionary Language

The PSLRA requires that forward-looking statements be accompanied by "meaningful cautionary statements" in order for safe harbor protection to apply. GSC Partners CDO Fund v. Washington, 368 F.3d 228, 243 (3d Cir. 2004). "Cautionary language must be extensive and specific." Id., at 243 n. 3. (also noting that "cautionary statements must be substantive and

tailored to the specific future projections, estimates or opinions . . . which the plaintiffs challenge") (citing Semerenko v. Cendant Corp., 223 F.3d 165, 182 (3d Cir. 2000)). Cautionary language must also be "directly related to the alleged misrepresentations, but it does not have to actually accompany the alleged misrepresentation." GSC Partners, 368 F.3d at 243 n. 3 (citation omitted).

Defendants direct the Court to cautionary language contained in eight documents, including Egalet's FY2014 Form 10-K, which predates the Class Period. See MTD Ex. 12–19 (Events #1, 3, 5–6, 10, 12–13, and FY2014 10-K).[14] Cautionary language took the form of warning readers (or listeners) that forward-looking remarks regarding future events," were not "guarantees of future performance," and directed those readers to the "risks and uncertainties . . . noted in" their "press release[s] and Egalet's filings with the SEC." See, e.g., MTD Ex. 12, at 1; Avaya, 564 F.3d at 258 (finding statements contained in SEC filings to be meaningful cautionary statements where, "[i]n each conference call and press release, defendants . . . specifically directed readers to [the company's] SEC filings"). Egalet's warnings specifically address both "known and unknown uncertainties and risks," including "our ability to obtain regulatory approval of our product candidates." See, e.g., MTD Ex. 14, at 2. However, the most comprehensive cautionary language appears in Egalet's Form 10-K's, filed with the SEC. See MTD, Ex. 18–19. These annual, publicly available filings contain, among other warnings, the following cautionary language:

[14] The Court may consider the cautionary language contained in these documents under both the language of the Safe Harbor Provision and Third Circuit precedent interpreting it. See 15 U.S.C. § 78u–5(e) ("On any motion to dismiss based upon [the Safe Harbor Provision], the court shall consider any . . . cautionary statement accompanying the forward-looking statement, which [is] not subject to material dispute, cited by the defendant."); In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1331 (3d Cir. 2002) (affirming judicial notice of documents filed with the SEC).

- "The commercial success of our product candidates will depend upon our ability to obtain FDA approved labeling describing their abuse-deterrent features or benefits. Our failure to achieve FDA approval of product labeling containing such information will prevent or substantially limit our advertising and promotion of the abuse-deterrent features of our product candidates in order to differentiate them from other opioid products containing the same active ingredients. This would make our products less competitive in the market." (MTD Ex. 18, at 50; Ex. 19, at 40)
- "[T]here can be no assurance that our product candidates in development will receive FDA-approved labeling that describes the abuse-deterrent features of such products." (MTD Ex. 18, at 50; Ex. 19, at 41)
- "[W]e may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate." (MTD Ex. 18, at 49; Ex. 19, at 40)
- "[T]he FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates." (MTD Ex. 18, at 49; Ex. 19, at 40)

Plaintiffs assert that the "cautionary language Defendants cite is boilerplate language" because they did not "alert[] investors to contemporaneously known specific risks that MorphaBond approval . . . likely precluded the FDA from granting ARYMO [] approval for a label that also included intranasal abuse deterrence." MTD Response, at 30–31.[15] In other

[15] For support, Plaintiffs cite several out-of-circuit cases, as well as In re Westinghouse Securities Litigation, 90 F.3d 696, 709 (3d Cir. 1996), for the proposition that "[w]arnings of possible adverse events are insufficient to make omissions of present knowledge of certain future events legally immaterial." MTD Response, at 31.

In re Westinghouse is a case involving the "bespeaks caution" doctrine, which, like the Safe Harbor Provision, requires that courts consider statements in context, that is, along with "accompanying statements." In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig., 7 F.3d 357, 364 (3d Cir. 1993). "While the Third Circuit has incorporated much of the 'bespeaks caution' doctrine into its analysis of the PSLRA . . . the Third Circuit has repeatedly distinguished the two concepts." Nat'l Junior Baseball League v. Pharmanet Dev. Grp. Inc., 720 F. Supp. 2d 517, 534 (D.N.J. 2010). [N]oticably absent" from the Safe Harbor Provision is "the stricter language" of the bespeaks caution doctrine, id., which requires that "cautionary language . . . ***render[] the alleged omissions or misrepresentations immaterial as a matter of law***." In re Trump, 7 F.3d at 371 (emphasis added).

In contrast, the "safe harbor . . . reaches further than the bespeaks caution doctrine," In re MobileMedia Sec. Litig., 28 F.Supp.2d 901, 930 (D.N.J. 1998), by immunizing from liability

words, Plaintiffs assert that Defendants' cautionary language is not sufficiently "tailored to the specific future projections" that Plaintiffs challenge as fraudulent misstatements or omissions. GSC Partners, 368 F.3d at 243 n. 3 (citation omitted).

The Court disagrees. The cautionary language cited by Defendants is at a level of specificity sufficient under established precedent. See, e.g., Avaya, 564 F.3d at 257; See In re Aetna, 617 F.3d at 283. The warnings contained in Egalet's SEC filings, presentations, and investor calls specifically address the risk that the FDA would fail to approve labeling for certain abuse-deterrence claims. For example, as excerpted above, Egalet repeatedly disclosed that "there can be no assurance that our product candidates in development will receive FDA-approved labeling that describes the abuse-deterrent features of such products." (MTD Ex. 18, at 50; Ex. 19, at 41) As Plaintiffs allege in the Amended Complaint, at the beginning of the Class Period, Egalet had only two late-stage lead product candidates in development. (CAC ¶ 35) Yet, Plaintiffs assert that Defendants' risk disclosures were insufficiently tailored because they did not specifically say it was ARYMO that might not receive intranasal abuse-deterrent labeling, and that it was MorphaBond's exclusivity that might prevent such labeling. However, Egalet was not required, as a matter of law, to precisely mention all abuse-deterrent labeling that might or might not be included, nor the specific reasons for the FDA's decisions. See OFI Asset Mgmt., 834 F.3d at 502 (finding statements supplied "sufficient context to constitute cautionary

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those forward-looking statements which, as mentioned above, are "identified as [] forward-looking [and] accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u–5(c)(1)(A)(i). Thus, although Plaintiffs are correct that, under the "bespeaks caution" doctrine, "[w]arnings of possible adverse events are insufficient to make omissions of present knowledge of certain future events legally immaterial," MTD Response, at 31, this legal rule is far from conclusive in this Court's Safe Harbor inquiry.

language," even though its "warnings could have been more direct"). Adopting Plaintiffs' asserted rationale would restrict the protection afforded by the Safe Harbor to confines unrecognized by any precedent.

It is sufficient that, for example, Defendants warned they "may not be allowed to include the labeling claims necessary or desirable for the successful commercialization" of its products in development. (Ex. 19, at 40) This statement—and others, such as, "the commercial success of our product candidates will depend upon our ability to obtain FDA approved labeling describing their abuse-deterrent features or benefits" (MTD Ex. 18, at 50)—gives notice to investors that Egalet might not be able to successfully commercialize its products if precluded (by the FDA) to use labeling that describes all abuse-deterrent features. Given that this is the precise risk Plaintiffs assert was responsible for their loss, this Court finds the cautionary language sufficient for purposes of the Safe Harbor Provision. See Avaya, 564 F.3d at 257 (finding cautionary language sufficient where the company "included in a list of [] 'risks and uncertainties' the very 'price and product competition' Shareholders assert was responsible for Avaya's missing its projections").[16] All of the Challenged Forward-Looking Statements are protected by the Safe Harbor Provision.

(2) Misrepresentation or Omission

The first pleading requirement of a Section 10(b) claim, subject to a "heightened pleading requirement[] above the normal Rule 12(b)(6) standard," Williams v. Globus Med., Inc., 869 F.3d 235, 240 (3d Cir. 2017), is that "the complaint must specify each allegedly misleading

[16] Plaintiffs here have also failed to show that Defendants' forward-looking statements were made with actual knowledge of their falsehood. 15 U.S.C. § 78u–5(i)(1)(B); see *infra*, discussing scienter.

statement, why the statement was misleading, and if an allegation is made on information and belief, all facts supporting that belief with particularity." Avaya, 564 F.3d at 252 ((internal quotations omitted) (citing 15 U.S.C. § 78u-4(b)(1)).

"[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" Matrixx, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)). "Silence, absent a duty to disclose, is not misleading under Rule 10b-5." Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988). The Third Circuit has made clear that "[e]ven non-disclosure of material information will not give rise to liability under Rule 10b-5 unless the defendant had an affirmative duty to disclose that information." Oran v. Stafford, 226 F.3d 275, 285 (3d Cir. 2000). The duty to disclose arises "when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure." Id. at 285–86.

Plaintiffs characterize their case as being "about Defendants' misleading statements to investors regarding the potential for ARYMO [] to receive broad labeling including intranasal abuse deterrence despite knowing that a serious risk existed that the FDA would not grant such a broad label following MorphaBond's approval." (MTD Response, at 30) Plaintiffs' theory of liability thus centers on allegations that Defendants deliberately hid from its investors that MorphaBond had been approved, and received exclusivity,[17] one month prior to the beginning of

[17] The exact moment when ARYMO received exclusivity is disputed by the parties and unresolved by documentary evidence. Thus, Plaintiffs' allegations are accepted as true. Nevertheless, the CDER Memo makes clear that the **scope** of MorphaBond's exclusivity was not decided by the FDA until late November, 2016, after the Class Period had ended. (See CDER Memo, at 13, *infra*)

the Class Period. In other words, Plaintiffs' theory is that Defendants' statements were misleading because they failed to disclose MorphaBond's regulatory status. Instead, Egalet continued discussing its process for seeking FDA approval of ARYMO, including for its ability to deter intranasal abuse, without mentioning that MorphaBond would preclude Egalet from making intranasal abuse deterrence claims on ARYMO's label.

This theory fails, in part because Defendants did not make false or misleading statements or omissions about ARYMO's prospects for approval.[18] The following examples, drawn from the Amended Complaint, are representative:[19]

Egalet stated that ARYMO's NDA "submission [to the FDA] includes a comprehensive battery of abuse-deterrent studies (Category 1, 2 and 3) which were conducted to support abuse-deterrent label claims for intravenous injection, snorting and oral abuse." (CAC ¶ 171) The fact that the studies were conducted to support label claims is not false. It is also not misleading, even when viewed in the light most favorable to Plaintiffs. The CDER Memo makes clear that the scope of MorphaBond's exclusivity was not decided by the FDA until November, 2016, after the Class Period had ended. See CDER Memo, at 13. Thus, during the Class Period, Egalet's description of its studies as being "conducted to support abuse-deterrent label claims for . . . snorting," would not mislead a reasonable investor into thinking that intranasal abuse-deterrent labeling was a guarantee. (CAC ¶ 171) This is especially the case because Egalet repeatedly disclosed that "there can be no assurance that our product candidates in development will receive FDA-approved labeling that describes the abuse-deterrent features of such products," (MTD Ex.

[18] It also fails because Plaintiffs fail to adequately allege scienter, see *infra*.

[19] The Court finds that all of the statements identified in the Amended Complaint, including the Challenged Forward-Looking Statements, were not false and misleading at the time they were made. The examples cited in this section are for illustrative purposes only.

18, at 50; Ex. 19, at 41) and "we may not be allowed to include the labeling claims necessary or desirable for [] successful commercialization." (Ex. 19, at 40)[20]

Egalet also represented in several of its Form 8-K's that it was "potential" for ARYMO to receive an intranasal abuse-deterrent label from the FDA.[21] (CAC ¶¶ 130, 147, 157, 166, 202) Again, Plaintiffs allege these statements were false and misleading because Egalet omitted to disclose the fact that MorphaBond had been approved by the FDA. (See, e.g., CAC ¶ 148) More specifically, Plaintiffs allege they were false and misleading because MorphaBond appeared to meet the regulatory requirements for a scope of labeling exclusivity that extended to abuse-deterrent intranasal abuse (and thus "would" receive such exclusivity). (Id. ¶ 109, 221) However, one cannot plausibly contend that a company using the word "potential" to describe an event (in this case, approval for intranasal abuse-deterrent labeling) misleads its investors because it appears in retrospect that the event was "unlikely." In re NAHC, 306 F.3d at 1330 ("To be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events."). Again, the Court finds it implausible in light of Egalet's risk disclosures that Egalet's use of the term "potential" could mislead reasonable investors into thinking that there were no obstacles to AMYRO receiving approval for intranasal labeling (such as MorphaBond's scope of exclusivity extending into this labeling area), see *supra*.

[20] Similar statements describing the results of ARYMO's studies and the fact that they "support" intranasal abuse-deterrence labeling, appear throughout the Amended Complaint. (See CAC, e.g., ¶¶ 123–24, 134, 138, 157) These statements are likewise not false or misleading for the reasons discussed above.

[21] Although Defendants did not specifically reference these statements as forward-looking, they appear to qualify as forward-looking statements protected by the Safe Harbor Provision.

One case relied on heavily by Plaintiffs to support the "misleading or false statement or omission" element of their Section 10(b) claim is In re Enzymotec Secs. Litig., No. 14-cv-5556, 2015 WL 8784065 (D.N.J. Dec. 14, 2015). In Enzymotec, the defendant company had directly made statements in press releases that it was aware of "recent changes in Chinese regulations," but also stated that "[t]he Company does not expect this change in Chinese regulations to impact its 2014 revenues." Id. at 14. The court concluded that the company had failed to disclose material information about the specific risk posed by a change in Chinese regulations, despite the fact that the regulations were public. Id.[22]

This Court declines to borrow from the logic of Enzymotec, and in any event, finds it distinguishable in one very important regard. In that case, the court was unpersuaded by the defendant's contention that the effect of the Chinese regulations on Enzymotec's revenues was uncertain. Thus, the latent uncertainty in that case did not excuse the company's failure to inform its investors in greater detail about the Chinese regulations that were already promulgated but yet to be implemented. In contrast, in this case, the regulatory conclusion of the FDA (a third-party) was the uncertainty. By way of illustration, for example, if the FDA had already decided the scope of Morphabond's exclusivity over intranasal labeling and Egalet were speculating about the effect of the FDA's determination, Egalet would be expected to provide

[22] The Enzymotec court's analysis did not discuss any argument regarding the public nature of the Chinese regulations as a basis for undermining scienter allegations, instead basing its conclusion that there was scienter almost exclusively on specific allegations of exceptionally large and unusually-timed stock sales by ten corporate insiders (not made pursuant to 10b5-1 trading plans) made near the time of the stock's high price, which amounted to $54.3 million. Id. at *19 ("Crucially, Lead Plaintiffs specifically tie together the timing of these sales with the core of the alleged misrepresentations: at the time of the [sales], Defendants were aware, or should have been aware, of the severe negative impact that the impending Chinese regulations would have on the Company's business").

accurate, or at least not misleading, information about the effect of the FDA's determination. Instead, in this case, a third-party, the FDA, had not yet determined the scope of MorphaBond's exclusivity. Therefore, when Egalet stated that it was "potential" for its drug to receive intranasal labeling from the FDA, it did not mislead reasonable investors; falsity is determined at the time a statement is made, not on the basis of subsequent events. See, e.g. Kovtun v. VIVUS, Inc., No. 10-cv-4957, 2012 WL 4477647, at *13 (N.D. Cal. Sept. 27, 2012), aff'd sub nom. Ingram v. VIVUS, Inc., 591 F. App'x 592 (9th Cir. 2015) ("[T]he statement that defendants expected that the FDA would approve Qnexa can at most be considered a reflection of a bad guess about an event that had not yet occurred. To say that investors were defrauded by defendants' statements about what a third party (the FDA) was going to do in the future is simply not plausible.").

(3) Scienter

The PSLRA imposes an additional pleading requirement for cases, like the present one, brought under Section 10(b) of the Securities Exchange Act of 1934. Under the PSLRA, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind [i.e., scienter]." 15 U.S.C. § 78u–4(b)(2)(A). This standard requires courts to take into account "plausible opposing inferences." Tellabs, 551 U.S., at 323. A complaint adequately pleads scienter under the PSLRA "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id., at 324. In making this determination, the court must review "all the allegations holistically." Id., at 326. The absence of a motive allegation, though relevant, is not dispositive. Id., at 325.

Plaintiffs dedicate more than 135 paragraphs of their Amended Complaint to allegations that Defendants' acted with scienter. See CAC ¶¶ 240–377. Specifically, Plaintiffs allege that, "Defendants knew or with deliberate recklessness disregarded that obtaining the intranasal abuse-deterrent labeling for ARYMO [] was impossibility [sic] or so unlikely that it was not a reasonable belief." For support, Plaintiffs point to the following alleged facts:[23]

- Defendants knew that ARYMO's value "is derived from the abuse-deterrent labeling," followed ARYMO's "abuse-deterrent opioid competition," and were "knowledgeable concerning the processes and regulatory framework for achieving abuse-deterrent labeling." (CAC ¶ 244) However, "[t]he market and the investing public . . . could not be expected to have know that MorphaBond's exclusivity would prevent ARYMO [] from receiving the intranasal abuse-deterrent labeling." (Id. ¶ 245) Defendants knew that MorphaBond met the regulatory requirements for achieving exclusivity for intranasal abuse-deterrent labeling. (See, e.g., id. ¶ 272)
- Defendant Radie "admitted" that MorphaBond's exclusivity was not a "surprise," and that "we had considered it, but we couldn't predict any definitive outcome based on previous exclusivity findings in this class." (Id. ¶ 230)
- Having reviewed a few of the documents referenced in Plaintiffs' Amended Complaint, Plaintiffs' "expert" John R. Thomas holds the "opinion that Egalet would have been well aware that that [sic] ARYMO [] would be precluded from receiving intranasal abuse-deterrent labeling." (Id. ¶ 284)
- "Egalet did not even seek approval of ARYMO [] without the condition of approval supporting [exclusivity-protected] intranasal labeling," which serves as an "admission by Defendants . . . that it could not . . . receive the intranasal abuse-deterrent labeling it sought." (Id. ¶ 296)
- In several of Defendants' investor presentation slideshows, there is a slide stating that "MorphaBond had intranasal labeling," which "serves as Defendants' own admission that they were aware of MorphaBond's labeling and its content." (Id. ¶ 302)
- Plaintiffs' confidential witness (CW1), an employee for a firm which was "contracted to serve as Egalet's dedicated specialty salesforce" reports that, "[d]ruing the sales representatives [sic] conference calls held in October and November 2016, Egalet executives informed the salesforce that ARYMO [] was encountering difficulties getting approved by the FDA with its proposed labeling." CW1 further reports "that the delay was related to the drug's labeling,

[23] The list is not intended to be comprehensive.

including the language touting ARYMO[‘s] abuse-deterrent properties." (Id. ¶ 331–34)

- Defendants were motivated to commit fraud, because:
  - "[b]y concealing the fact that Egalet was precluded from receiving the intranasal abuse-deterrent labeling for ARYMO [], Defendants were able to obtain secured debt financing." (Id. ¶ 336)
  - Defendant Radie sold $440,935 of stock (34% of his holdings), non-party Mark Strobek (Egalet COO) sold $512,868 of stock (64.2% of his holdings), Defendant Musial sold $334,666 of stock (46.5% of his holdings), and Defendant Dayno sold $19,944 of stock (12.5% of his holdings) (Id. ¶ 350)
- ARYMO's FDA approval for abuse-deterrent labeling constituted part of Egalet's "core operations," and Egalet is a relatively small company with only five products in development during the Class Period, so Defendants' scienter concerning such core operations can be inferred. (Id. ¶¶ 363–64)
- Egalet fired COO Melloy in May, 2016, in a manner inconsistent with "the reasons represented" by the company. (Id. ¶ 376)

Plaintiffs' scienter allegations are undermined by the public nature of the regulations that allegedly guided the FDA's determination as to ARMYO's approval for intranasal abuse-deterrent labeling. Indeed, Plaintiffs' own Amended Complaint acknowledges that all the information required to determine whether MorphaBond would obtain exclusivity was public in nature, stating "[i]n view of . . . publicly available information, Egalet, with knowledge of FDA law and practice[,] would comprehend that MorphaBond would obtain a three-year exclusivity . . . This inference would have been obvious . . . ." (Id. ¶ 275) Given that the legal requirements for labeling exclusivity are publicly-available in federal statutes and regulations, and Plaintiffs do not allege that Defendants possessed any insider or confidential knowledge beyond what was

"publicly available," any "inference [that] would have been obvious" to Defendants could similarly have been obvious to an informed investor using public information. (Id.).[24]

This relates to a similar issue. The Amended Complaint takes for granted that the scope of MorphaBond's exclusivity would extend into intranasal abuse deterrent labeling. However, the CDER Memo demonstrates that the FDA had not yet approved a scope of exclusivity for MorphaBond during the Class Period. (CDER Memo, at 13) Thus, Defendants could not have known during the Class Period that MorphaBond's labeling exclusivity would preclude intranasal abuse deterrent labeling for ARYMO. In re NAHC, 306 F.3d at 1330 ("[L]iability cannot be imposed on the basis of subsequent events."); Gallagher v. Abbott Labs., 269 F.3d 806, 810 (7th Cir. 2001) ("Unless [the defendant] had a time machine, it could not have described . . . a letter that had yet to be written."). In fact, it was far from certain that the FDA would grant MorphaBond such a scope of exclusivity, as the CDER Memo demonstrates that the FDA "considered but declined to adopt both broader and narrower potential approaches to the scope of exclusivity." (CDER Memo, at 13) The FDA also noted that it considered a scope of exclusivity "limited to the specific formulation in MorphaBond, or the specific technology MorphaBond uses to deter intranasal abuse." (Id., at 14) Because the FDA made its

[24] Similarly, Plaintiffs allege "that it was clear to Egalet that MorphaBond's three-year exclusivity would apply to the ARYMO ER 505(b)(2) NDA. Even before Egalet filed its 505(b)(2) NDA, a reasonable person with knowledge of FDA law and practice would have had to deliberately and recklessly disregard its import, or had an unreasonable belief that ARYMO ER could possibly still get intranasal abuse-deterrent labeling despite publicly available information." (CAC ¶ 278) Again, Plaintiffs themselves allege that publicly available information was sufficient to determine that ARYMO would not receive intranasal abuse-deterrent labeling. This substantially weakens Plaintiffs' scienter allegations.

determination after the Class Period, the inference that Defendants did not act with scienter is "at least as compelling" as an inference that they did. Tellabs, 551 U.S. at 324.

Plaintiffs also allege that ARYMO's NDA did not seek exclusivity-protected intranasal labeling, which they allege amounts to an admission that ARYMO could not receive such labeling at all. (CAC ¶ 296) They also allege that Defendants' slideshow presentations show awareness of MorphaBond's approval for intranasal labeling. (Id. ¶ 302) Both of these allegations are fully consistent with Defendants' knowledge that MorphaBond had FDA approval. However, Defendants do not refute that they were aware of MorphaBond's approval, and MorphaBond's approval is not at the heart of the issue in this securities fraud lawsuit. Instead, it is the scope of MorphaBond's exclusivity that is at issue, and, as detailed in the CDER Memo, the scope of such exclusivity was not determined until after the Class Period. See In re Westinghouse Sec. Litig., 90 F.3d 696, 713 (3d Cir. 1996) ("[T]he documents on which plaintiffs rely simply do not support their conclusory allegations.").

As for Plaintiffs' expert,[25] John R. Thomas, it is unclear what is added to the scienter allegations by his opinion, which was based solely on "the substance and documents referenced above in paragraphs 249-279." (CAC ¶ 283) The documents in those paragraphs are all publicly available information, and in fact, are mostly federal statutes and regulations. Professor

[25] The Court would likely be correct in choosing to entirely ignore Plaintiffs' expert's opinions. See, e.g., DeMarco v. DepoTech Corp., 149 F.Supp.2d 1212, 1221 (S.D. Cal. 2001) (allowing plaintiffs to rely on an expert's opinion in order to state securities claims requires a court to "confront a myriad of complex evidentiary issues not generally capable of resolution at the pleading stage"); Fin. Acquisition Partners LP v. Blackwell, 440 F.3d 278, 285 (5th Cir. 2006) ("Even if non-opinion portions of an expert's affidavit constitute an instrument pursuant to Rule 10, opinions cannot substitute for facts under the PSLRA."). Nonetheless, the Court declines to do so here because, even with the expert's opinions considered, the complaints fail in the face of a Rule 12 motion.

Thomas's opinion is that "Egalet would have known MorphaBond three-year exclusivity attached at the time MorphaBond was approved by the FDA." Again, this is not disputed by Defendants, because it is not at the heart of the issue in this litigation. Instead, the central issue is whether the scope of such exclusivity would extend into intranasal abuse-deterrent labeling. To the extent that Professor Thomas formed an opinion about the scope of MorphaBond's exclusivity, the fact that such an opinion is based solely on public information substantially undermines his conclusion (for the same reasons expressed above).[26]

Similarly, Plaintiffs' confidential witness does little to add to Plaintiffs' scienter allegations. The paragraphs pertaining to CW1 in the Amended Complaint lack multiple requirements of particularized pleading, including the "who, what, when, where and how" of the events at issue. GSC Partners, 368 F.3d at 239. CW1 reports that "Egalet executives" (without specifying who, or even whether it was one of the Individual Defendants), said ARYMO was "encountering difficulties getting approved by the FDA with its proposed labeling" (without specifying what particular difficulty, or even whether it related to intranasal as opposed to other abuse pathways), that the information was relayed during "calls held in October and November 2016," (without specifying when, during which call, or whether it happened more than once). (CAC ¶ 334)

[26] Importantly, Professor Thomas did not review the CDER Memo prior to forming his opinion. (See CAC ¶ 283 (stating only that Professor "Thomas has reviewed the substance and documents referenced above in paragraphs 249-279," paragraphs which do not include any discussion or reference to the CDER Memo); id. ¶ 284 (stating that, "[b]ased upon his review, it is Thomas's opinion that . . .")) The Court notes that this is not a circumstance in which the public information relied upon by the expert was "difficult to obtain." Pub. Employees Ret. Sys. of Mississippi, Puerto Rico Teachers Ret. Sys. v. Amedisys, Inc., 769 F.3d 313, 323 n. 3 (5th Cir. 2014) (cited by Enzymotec, 2015 WL 8784065, at *19 n. 19 (relied upon by Plaintiffs)).

Plaintiffs' allegations regarding the departure of COO Melloy in May, 2016, do not relate in any way to their allegations about ARYMO. Nonetheless, the Amended Complaint concludes that Melloy's "peculiar" departure "support[s] a cogent and compelling inference of scienter" because "some investors . . . held Melloy in very high esteem." (CAC ¶ 377) If there is a connection between Melloy's departure and Defendants' alleged scienter (or ARYMO's intranasal labeling), it cannot be inferred from anything in the Amended Complaint and it remains unexplained in Plaintiffs' brief.

With respect to Plaintiffs' "core operations" assertion, it is entirely reasonable to suggest that achieving FDA approval for ARYMO was one of Egalet's core operations. Thus, the "nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter." S. Ferry LP, #2 v. Killinger, 542 F.3d 776, 786 (9th Cir. 2008). However, knowledge of ARYMO's prospects for FDA approval in general is different from knowledge that ARYMO definitely would or would not receive approval for specific claims of abuse deterrence. See Avaya. 564 F.3d at 267–68 ("The pertinent question is whether all of the facts alleged, taken collectively give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."). Given that the scope of MorphaBond's exclusivity remained uncertain during the class period, Defendants cannot be attributed with knowledge that the FDA would eventually preclude ARYMO from making intranasal abuse deterrence claims.

Finally, Plaintiffs seek to bolster their scienter allegations by demonstrating that Defendants had "a motive to commit fraud." Avaya, 564 F.3d at 278. After Tellabs, 551 U.S. 308, it is clear that "motive and opportunity may no longer serve as an independent route to scienter," but instead may be used to "strengthen the inference of scienter." Avaya, 564 F.3d at

277–78. Here, Plaintiffs point to two alleged motives for Defendants to commit securities fraud: (1) to receive continued debt financing for Egalet, and (2) for financial gain through stock sales prior to revelation of the "truth." Both motives fail to advance Plaintiffs' scienter allegations, in light of substantial precedent finding both inadequate in like circumstances.

As to the first alleged motive, it is well-settled that ordinary business motives such as the need to obtain credit are general business motives that do not support an inference of scienter. See, e.g., Key Equity Inv'rs Inc. v. Sel-Leb Mktg. Inc., 246 F.App'x 780, 786 n. 10 (3d Cir. 2007) (an allegation that defendants committed fraud to maintain a line of credit is "nothing more than an ordinary business motive"); Rahman v. Kid Brands, Inc., 736 F.3d 237, 245–46 ("Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud.").

As to the second alleged motive, stock sales can support an inference of scienter where "the stock sales were unusual in scope or timing." Oran, 226 F.3d at 290 (3d Cr. 2000). However, Plaintiffs do not allege particularized facts as to the scope or timing of Defendants' stock trades, which is, along with other deficiencies in pleading scienter, "fatal of plaintiffs' case." Id., at 289 (finding an "absence of . . . information" about "whether the trades were normal and routine for each executive"). It is apparent on the face of the Form 4's filed with the SEC that Defendants' stock sales were made at the times at which each Defendant's restricted stock vested, and that the sales were made to pay the tax liability incurred as a result of the vesting. (See MTD Ex. 22 (footnote on each Form 4 states "Sale effected pursuant to a Rule

10b5-1 trading plan to pay tax liability on vesting restricted stock"))[27] This weighs heavily against an inference of scienter. In re Radian Sec. Litig., 612 F. Supp. 2d 594, 611 (E.D. Pa. 2009) (collecting cases supporting the proposition that stock sales covering tax liabilities weigh against an inference of scienter); Avaya, 564 F.3d at 279 (stock sales made pursuant to terms of a Rule 10b5-1 plan did not bolster scienter allegations); In re NutriSystem, Inc. Sec. Litig., 653 F. Supp. 2d 563, 576 (E.D. Pa. 2009) (finding stock transactions made pursuant to Rule 10b5-1 plan were not suspicious in the absence of any allegation that the plans were adopted when a defendant was aware of material non-public information).

Thus, having reviewed "all the allegations [of scienter] holistically," Tellabs, 551 U.S., at 326, this Court finds that the Amended Complaint does not support an inference of scienter that is "at least as compelling as any opposing inference one could draw from the facts alleged." Id., at 324.

The Court notes that Plaintiffs have relied heavily on a number of distinguishable and non-precedential district court cases to assert that they have fulfilled the scienter element of securities fraud.

One case on which Plaintiffs rely is In re Viropharma, Inc. Sec. Litig., No. 02-cv-1627, 21 F.Supp.3d 458 (E.D. Pa. Apr. 7, 2003). In Viropharma, the court denied the defendants' motion to dismiss the complaint, which was based on allegations that the company had made "public statements of confidence in the prospect of achieving an additional three years of exclusivity for [its drug], made while its [petition for exclusivity] was pending before the FDA." Id. at 471. However, unlike the allegations in any of Plaintiffs' three complaints in this case, in

[27] In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1331 (3d Cir. 2002) (affirming judicial notice of documents filed with the SEC).

Viropharma, the complaint directly alleged that "Viropharma had privately received [information] from the FDA regarding the [FDA's] view" that the study upon which defendant had based its petition for exclusivity was inadequate. Id. In fact, the plaintiff in Viropharma specifically alleged that the "FDA made it known to Defendants on five occasions that the [] study was inadequate." Id. at 473. Moreover, in Viropharma, there were scienter allegations of substantial and unusually timed stock sales (not pursuant to 10b5-1 trading plans) and various high-ranking confidential witnesses who attended discussions amongst the corporate defendant executives regarding drug exclusivity.

Another case meriting brief discussion here upon which Plaintiffs substantially rely is Frater v. Hemispherx Biopharma, Inc., 996 F. Supp. 2d 335 (E.D. Pa. 2014). In Frater, the court denied the defendants' motion to dismiss. As in Viropharma, the primary allegation was that the FDA had privately provided information to the corporate defendant regarding the prospects for drug approval, which the corporate defendant failed to disclose to its public shareholders. See id. at 350 (citing In re Mannkind Sec. Actions, 835 F.Supp.2d 797, 811 (C.D. Cal. 2011) ("When the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity.").

Plaintiffs also rely on In re PTC Therapeutics, Inc. Sec. Litig., No. 16-cv-1124, 2017 WL 3705801 (D.N.J. Aug. 28, 2017), in which the court explicitly acknowledged it was departing from "four cases in which allegations that defendants knew but misrepresented certain information about clinical data, which ultimately misled investors about the likelihood of FDA approval, were insufficient to repel a motion to dismiss." Id. at *18. (citing In re Columbia Laboratories, Inc. Secs. Litig., No. 12-cv-614, 2013 WL 5719599 (D.N.J. Oct. 21, 2013); Sapir v. Averback, et at., No. 14-cv-7331, 2016 WL 554581 (D.N.J. Feb. 10, 2016); In re Adolor Corp.

Secs. Litig., 616 F. Supp. 2d 551 (E.D. Pa. 2009); and In re Amarin Corp. PLC, No. 13-cv-6663, 2015 WL 3954190 (D.N.J. June 29, 2015)). In PTC, the court distinguished the "four cases" that ruled in favor of granting motions to dismiss on the grounds that, among other things, none of the drugs at issue in Columbia, Sapir, Adolor, or Amarin ever received an RTF [Refuse to File letter from the FDA], let alone two RTFs issued for essentially the same reason." PTC Therapeutics 2017 WL 3705801, at *18. It is worth noting that in this case, Plaintiff does not allege that the FDA sent any "Refuse to File" letters to Egalet prior to finding that Egalet would not obtain intranasal deterrent labeling for ARYMO.[28]

In summary, the present case is premised on allegations that Defendants possessed the requisite expertise to determine, based on admittedly public information, that it was unlikely to receive FDA approval for a particular type of labeling on its drug. Frater and Viropharma are premised on allegations that the FDA specifically imparted information, not available to the public, that reasonable investors would want to know in order to make an informed view as to the value of the company's stock. The complaint in Enzymotec, although factually closer to the present case, alleged nearly $60 million in insider stock sales, suspiciously timed, which specifically bolstered the plaintiffs' scienter allegations.

[28] Plaintiffs also rely on Walsingham v. Biocontrol Technology, Inc., 66 F. Supp. 2d 669 (W.D. Pa. 1998) where the court found that the complaint adequately alleged scienter because it alleged that "the defendants had knowledge of, and access to, information regarding flawed testing and test results which materially impacted FDA approval." Id. at 675. That sentence is one of only two sentences in the entire opinion that addresses the complaint's specific allegations vis-à-vis the 10(b) scienter element, making it impossible for this Court, and others, to determine what that court found important in its scienter analysis. Also of note, Walsingham predates Tellabs by nearly a decade, and is called into question, if not abrogated entirely, by Tellabs' holding regarding the cogency of inferences about scienter.

Therefore, this Court reiterates that Plaintiffs' citations, while non-precedential, are also factually inapposite in this context. Plaintiffs' allegations of securities fraud under Section 10(b) must be dismissed.

D. Section 20(a) Claims

Because Plaintiffs fail to state a claim under Section 10(b), their Section 20(a) control person liability claim must also be dismissed. Shapiro v. UJB Fin. Corp., 964 F.2d 272, 279 (3d Cir. 1992) ("[O]nce all predicate § 10(b) claims are dismissed, there are not allegations upon which § 20(a) liability can be based.").

VI. Leave to Amend

In general, dismissals under Rule 12(b)(6) are not immediately final or on the merits. Third Circuit cases are clear that leave to amend should be refused "only on the grounds of bad faith, undue delay, prejudice, or futility." See, e.g., Alston v. Parker, 363 F.3d 229, 236 (3d Cir. 2004) (citing Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000)). Defendants have not suggested bad faith, undue delay, or prejudice. Unless amendment would be futile, the Court must grant Plaintiffs leave to file another amended complaint.

A finding of futility is proper when "the complaint, as amended, would fail to state a claim upon which relief could be granted." In re Burlington, 114 F.3d at 1434 (citation omitted). In determining whether a claim would be futile, the district court applies the same standard of legal sufficiency as applies under Fed. R. Civ. P. 12(b)(6). Id.

Plaintiffs have offered a proposed third complaint as part of their Motion for Leave to File a Second Amended Complaint. This proposed complaint mirrors the First Amended Complaint in most material respects. It does not contain any additional allegations that change

the Court's analysis, and in fact, contains nearly no new information at all (aside from conclusory statements).

However, the Second Amended Complaint emphasizes a scienter argument that Plaintiffs previously made, albeit less strongly, alleging that Egalet's decision in its NDA not to seek exclusivity for ARYMO's intranasal abuse deterrence labeling claims amounted to a tacit admission that Defendants knew they could not receive intranasal abuse deterrent labeling at all. However, this theory is not new, as it was previously included in the second complaint and discussed at the first oral argument, held on February 20, 2018 (prior to the filing of the proposed third complaint):

> The Court: Okay. All right. Number eight. How does Egalet's decision not to seek exclusivity for ARYMO amount to an admission, as alleged by plaintiff, that ARYMO could not receive such labeling at all? Are there other plausible reasons that Egalet might not seek exclusivity when filing an NDA for its product?
> . . .
> Plaintiffs' Counsel: [T]he fact that they . . . didn't actually ask for exclusivity suggests that they knew at the time of the NDA that in fact their drug did not qualify for exclusivity. And if it didn't qualify for exclusivity, then Morphabond must - - it would only not qualify for exclusivity if Morphabond did qualify for exclusivity.

(ECF 39, at 19:15-20:8)

Here, it is important to note that Plaintiffs do not allege that Defendants made false or misleading statements or omissions regarding the prospects for ARYMO's intranasal labeling exclusivity, but rather the prospects for ARYMO's approval. While it is correct that Defendants did not seek exclusivity along with ARYMO's approval, this can reasonably be traced to explanations other than fraud. Most notably, it suggests that Egalet was aware of Inspirion's application for MorphaBond, which by virtue of containing the same active moiety (i.e., portion

of a molecule), would, irrespective of its scope of its exclusivity, preclude ARYMO from receiving exclusivity (but not necessarily FDA approval). In any event, Plaintiffs' renewed emphasis on this argument in the Second Amended Complaint does not materially change any part of the Court's above analysis related to scienter or otherwise.[29]

Thus, the Court concludes that amendment would be futile.

VII. Conclusion

After extensive briefing and two oral arguments, Plaintiffs still fail to adequately plead particularized scienter, as required under the PSLRA, related to any omission or false statement supported by any reported precedent, controlling or otherwise. Plaintiffs' allegations do not show Defendants omitted or concealed anything internal to Egalet—or possible action or inaction by the FDA—and Defendants cannot be held responsible for action or inaction taken by the FDA.

For the foregoing reasons, Plaintiffs' Motion to Strike is DENIED and Defendants' Motion to Dismiss is GRANTED WITH PREJUDICE.

An appropriate Order follows.

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[29] The other additions made in the proposed Second Amended Complaint largely allege that a Cantor Fitzgerald analyst and a Guggenheim Securities analyst "did not appreciate" that MorphaBond's FDA approval created a risk that ARYMO might not receive intranasal abuse-deterrent labeling. These allegations do not alter the Court's conclusion that Plaintiffs' allegations fall short of alleging securities fraud.